



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 10, 2015

Nibec Co., Ltd.
c/o Takashi Yamada
CEO and Regulatory Affairs
Smile US
22395 South Western Avenue, Suite 304
Torrance, California 90501

Re: K150079

Trade/Device Name: Regenomer® Syringe, Regenomer® Plug, Regenomer® Block
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: November 3, 2015
Received: November 9, 2015

Dear Takashi Yamada:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.0 Indications for Use Statement

INDICATION FOR USE

510(k) Number: K150079

Device Name: Regenomer® Syringe
Regenomer® Plug
Regenomer® Block

INDICATIONS FOR USE:

The Regenomer® is in general recommended for the filling of extraction sockets and periodontal defect. The indication for use depending on the device format is further classified as described in following table.

Format	Syringe	Plug	Block
Indication for use	- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) - Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)	- Filling of extraction sockets - Augmentation or reconstructive treatment of the alveolar ridge -Elevation of maxillary sinus floor	- Augmentation or reconstructive treatment of the alveolar ridge -Elevation of maxillary sinus floor

Prescription Use ✓

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2.0 510(k) Summary

Sponsor/Applicant

NIBEC Co., Ltd.
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 Chungcheongbuk-do, 27816, Korea
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 Contact: Dr. Park, Yoon-Jeong

Date Prepared : November 30, 2015

Prior Submission : There were no prior submissions.

Device Name and Identification

Proprietary Name:	Regenomer® Syringe
	Regenomer® Plug
	Regenomer® Block
Common/Usual Name:	Bone Filling Augmentation Material
Classification Name:	Bone grafting material

Predicate devices

Primary predicate

FOUNDATION Bone Filling Augmentation Material (K040783)
 Manufactured by:
 Terumo Corporation
 44-1, 2 chome
 Hatagaya, Shibuya-ku
 Tokyo 151-0072
 Japan

Reference predicates

Bio-Oss® Collagen (K092428, K033815, K974399)
 Manufactured by:
 Geistlich Pharma AG
 Bahnhofstrasse 40
 CH-6110 Wolhusen
 Switzerland

Device Category/Class

Device Class: Class II
 Regulation Number: 21 C.F.R. 872.3930
 Product Code: NPM

Indication for use

The Regenomer® is in general recommended for the filling of extraction sockets and periodontal defect. The indication for use depending on the device format is further classified as described in following table.

Format	Syringe	Plug	Block
Indication for use	<ul style="list-style-type: none"> - Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) - Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR) 	<ul style="list-style-type: none"> - Filling of extraction sockets - Augmentation or reconstructive treatment of the alveolar ridge -Elevation of maxillary sinus floor 	<ul style="list-style-type: none"> - Augmentation or reconstructive treatment of the alveolar ridge -Elevation of maxillary sinus floor

Device Description

Regenomer® is a sponge-like absorbable and porous collagen designed to be used as bone filling augmentation material. The device is manufactured from purified type I collagen derived from porcine skin sources in South Korea. The porcine skin is certified by veterinarian and is obtained by a standardized controlled manufacturing process. Regenomer® is manufactured in three types, Regenomer® Syringe (sheet shape in syringe and blister), Regenomer® Plug (bullet shape in blister), and Regenomer® Block (block shape in blister). Regenomer® are supplied sterile, non-pyrogenic, and for single use only.

Basis for Substantial Equivalence

Regenomer® is substantially equivalent for purposes of the FDA's medical device regulations to FOUNDATION®, which is cleared for the filling of extraction sockets (K040783) and Bio-Oss® Collagen (K974399), which was cleared for the filling of extraction sockets and other bone augmentation procedures. The differences in indications for Regenomer® compared to the predicates do not change the intended use because all are intended for bone augmentation procedures. While Regenomer® is indicated for more specific indications based on device shape and size, this is substantially equivalent to the predicates and does not change the intended use because all are intended for bone augmentation procedures. Bio-Oss® Collagen has block type product, the size range of 6X6X6, 7X8X9, 9X10X11 mm. The size dimension of Regenomer Block type is 6X5X7 and 8X7X9mm, which is 10% of size difference with the dimension of Bio-Oss® Collagen. Intended use, principles of operation, and technological characteristics are substantially equivalent to the corresponding characteristics of the predicate devices. Although minor technological differences exist, Regenomer® and the predicate device, these minor differences raise no new issues of equivalence of Regenomer® with predicate devices.

The following is a table comparing Regenomer®, FOUNDATION®, and Bio-Oss® Collagen cleared for the filling of extraction sockets.

Table 1: Substantial Equivalence Comparison

ITEM	Regenomer®	FOUNDATION® (K040783)	Bio-Oss® Collagen (K092428, K033815, K974399)
Intended Use	<p>Syringe type</p> <ul style="list-style-type: none"> - Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) - Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR) <p>Plug type</p> <ul style="list-style-type: none"> - Filling of extraction sockets - Augmentation or reconstructive treatment of the alveolar ridge - Elevation of maxillary sinus floor <p>Block type</p> <ul style="list-style-type: none"> - Augmentation or reconstructive treatment of the alveolar ridge - Elevation of maxillary sinus floor 	<p>The FOUNDATION device is a collagen-based bone filling augmentation material for use in the filling of extraction sockets.</p>	<ul style="list-style-type: none"> - Augmentation or reconstructive treatment of the alveolar ridge. - Filling of intrabony periodontal defects. - Filling of defects after root resection, apicoectomy, and cystectomy - Filling of extraction sockets - Elevation of maxillary sinus floor - Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR) - Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)
Target population	Human oral, periodontal	Human oral, periodontal	Human oral, periodontal
Dosage form	Syringe (sheet shape in syringe and blister, 25, 50mg) Plug (Bullet shape in blister, 10X20, 12X25mm) Block (Block shape in blister, 6X5X7, 8X7X9mm)	Bullet shape (8X25, 15X25mm) sheet type (25X25, 50X25mm) Heat-sealed aluminum package	a block form in a blister

Dimension	Format	Sizes (mm)		Weight (mg/unit)		Format	Sizes (mm)		0.25mm to 1.0mm or 1.0mm to 2.0mm granules					
	Syringe	Small	20X10X1 .8	25		sheet	Small	25X25						
		Medium	25X15X1 .8	50			Medium	50X25						
	Plug	small	10 x 20	40		Plug	small	8 x 25						
		medium	12 X 25	100			medium	15 X 25						
	Block	small	6 X 5 X 7	10			Shape	Dimension (mm)	Weight (g)					
		medium	8 X 7 X 9	20			Block	6X6X6	100mg					
										Block	7X8X9	250mg		
										Block	9X10X11	500mg		
Material	Type I collagen			Type I collagen 85-95% Type III collagen 5-15%			Anorganic derived osteoconductive hydroxyapatite, Collagen							
Source bone	NA			NA			Bovine							
Source of collagen	Porcine			Bovine			Porcine							
Physical Morphology	Sponge			Sponge			Trabecular, interconnecting macro and micro pores							
Biocompatibility	Biocompatible, as demonstrated by : - Acute systemic injection test - AMES test - Cytotoxicity test - Implantation test - Intracutaneous reactivity test - Micronucleus Test for Genetic Toxicology - Maximization and			Biocompatible (as demonstrated in published literature)			Biocompatible (as demonstrated in published literature)							

	<p>sensitization test</p> <ul style="list-style-type: none"> - Oral Mucosa Irritation test - Sterility test - Pyrogen test - Preclinical safety and efficacy test - Clinical case series 		
Performance	Bone filling	Bone filling	Bone formation
Compatibility w/other devices			Can be used with GTR membrane
Sterilization Process	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation
Chemical safety	Biocompatible	Biocompatible	Biocompatible
Anatomical sites	Oral, Periodontal	Oral, Periodontal	Oral, Periodontal
Non-Pyrogenic	Yes	Yes	Yes
Shelf-Life	36 Months	36 Months	36 Months

Brief Summary of Data Submitted

The Sponsor evaluated the performance characteristics of Regenomer® and FOUNDATION® with a thorough chemical and physical characterization including pH, loss on drying, DSC analysis, amino acid contents, FT-IR, SDS-PAGE, sterility, and bacterial endotoxin. The physical and chemical characteristics of Regenomer® were found to be comparable with FOUNDATION®. Both products were found to grow new bone and be subsequently resorbed at similar rates in canine alveolar bone defects model. Finally, in a clinical case series, use of Regenomer® resulted in defect healing and formation of new bone without inflammation.

Regenomer® was the subject of the full range of biocompatibility tests recommended in the FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Devices" and in accordance with ISO 10993. Test results confirmed product biocompatibility. Regenomer® is made from pure type I collagen obtained by a standardized controlled manufacturing process. The type I collagen has been purified from veterinary certified porcine skin. Further, the product is sterilized by γ -irradiation to achieve a sterility assurance level SAL 1×10^{-6} .

Based on the information presented herein, it has been demonstrated that Regenomer® is substantially equivalent to FOUNDATION® for the proposed indications for use.

Conclusion

The Regenomer® presents the same types of potential risks to consumers as the predicate device FOUNDATION®, and has controlled these risks in a similar manner. Comparison with the predicate device shows that the device has similar specification, physico-chemical properties, and performance. In addition, biocompatibility tests show that Regenomer® meets the requirements of those standards. Therefore, it is concluded that Regenomer® is substantially equivalent to the predicate device FOUNDATION®.